

complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

E. For original BLA and BLA efficacy supplement resubmissions:

1. Class 1 resubmitted applications are applications resubmitted after a complete response letter that include the following items only (or combinations of these items):

- (a) Final printed labeling
 - (b) Draft labeling
 - (c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
 - (d) Stability updates to support provisional or final dating periods
 - (e) Commitments to perform Phase 4 studies, including proposals for such studies
 - (f) Assay validation data
 - (g) Final release testing on the last 1-2 lots used to support approval
 - (h) A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
 - (i) Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
 - (j) Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.
2. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

THE SECRETARY OF HEALTH AND
HUMAN SERVICES,

Washington, DC, November 14, 2002.

Hon. EDWARD KENNEDY,
U.S. Senate,
Washington, DC.

DEAR MR. CHAIRMAN. As you are aware, the Medical Device User Fee and Modernization Act of 2002 was signed by the President on October 26, 2002. Under Title I, the additional revenues generated from fees paid by the medical device industry will be used to expedite the medical device review process, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with the industry.

FDA has worked with various stakeholders, including representatives from consumer, patient, and health provider groups, and the medical device industry to develop legislation and goals that would enhance the success of the device review program. Title I of the Medical Device User Fee and Modernization Act of 2002 reflects the fee mechanisms and other improvements developed in these discussions. The performance goals referenced in Section 101 are specified in the enclosure to this letter, entitled "Performance Goals and Procedures." I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources identified in the bill.

This letter and the enclosed goals document pertain only to title I (Fees Related to Medical Devices) of Public Law 107-250, Medical Device User Fee and Modernization Act of 2002. OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the authorization of this vital program.

Sincerely,

TOMMY G. THOMPSON.

LOCAL LAW ENFORCEMENT ACT OF 2001

Mr. SMITH of Oregon. Mr. President, I rise today to speak about hate crimes legislation I introduced with Senator KENNEDY in March of last year. The Local Law Enforcement Act of 2001 would add new categories to current hate crimes legislation sending a signal that violence of any kind is unacceptable in our society.

I would like to describe a terrible crime that occurred September 6, 2001 in Madison, WI. Two men were arrested on the University of Wisconsin campus for attempting to strangle a gay man. The attackers were part of a visiting group on campus to talk about homosexuality. The attackers approached the victim, told him that it was his time to go to hell, then began choking him.

I believe that government's first duty is to defend its citizens, to defend them against the harms that come out of hate. The Local Law Enforcement Enhancement Act of 2001 is now a symbol that can become substance. I believe that by passing this legislation and changing current law, we can change hearts and minds as well.

ELECTRIC ASSISTED LOW-SPEED BICYCLES

Mr. JEFFORDS. Mr. President, I am very pleased that H.R. 727 will soon be on its way to the President for signature.

This bill, which passed the other body by a 401 to 1 margin on March 6, 2002, will help promote the use of electric-assisted low-speed bicycles and will help seniors participate in cycling related activities. For many of our seniors, long-distance bicycle rides or participation in bicycle clubs in areas with extensive hills, can present an unfair challenge.

Simply put, this bill will allow seniors to more fully participate in these events while, at the same time, providing solid exercise for them. I believe that in states, such as my home state of Vermont, our senior citizens may derive benefits from using these low-speed pedal-assisted electric bicycles for help getting up our steep terrain.

Not only will these bikes improve mobility options for seniors, they will also help to reduce congestion on our roads and air pollution when used for commuting purposes. Since these bikes produce no noise or exhaust because they are powered by small batteries rather than gasoline powered engines, they provide an environmentally friendly transportation option to our citizens and should be treated as bicycles and not as motor vehicles.

H.R. 727 states that these low-speed pedal-assisted electric bikes, as defined in very detailed Consumer Product Safety Commission, CPSC, rules—found at 16 CFR 1512—shall be considered bikes and not motor vehicles.

These detailed existing safety standards for bicycles should be applied in

every state, as in current law, and as would be required under the bill for these low-speed pedal-assisted electric bikes. The existing safety rules are based on extensive experience and tests done on material strength, stem and fork torque resistance, pedal design and the like and should apply throughout the nation. The existing rules, referenced in H.R. 727, set the requirements for such things as: handlebar stem insertions; pedal construction; chain guards; handlebar stem tests; stem-to-fork clamp tests; bicycle design; handlebar strength; front hub retention; attachment hardware; hand levers for brakes; reflectors; pedal reflectors; seat size; maximum seat height; and the like.

To assure the safety of these bicycles, the bill provides for federal preemption of State law or requirements—as provided in section 1(d) of the bill—regarding those detailed CPSC safety rules. The CPSC would have the authority to issue additional federal rules regarding the construction and physical properties of these low-speed bicycles to ensure safety.

Obviously, local regulation of where these low-power bicycles can be ridden, such as not on sidewalks if that is the state or local rule, or not on high-speed thruways, or whether helmets are required, would still be a local matter. Local or state governments would continue to regulate the use of these and other bikes, who could ride the bikes, and where they could be ridden, but they could not alter the safety rules for the construction of the bikes, or the metals or materials to be used for that construction, which would be in the hands of the CPSC.

H.R. 727 also specifies a 20 mph limit on speed, on a flat surface, for these electric assisted bikes. The bikes covered by this bill look similar to "regular" low-weight bicycles and will have similar speeds but require less human leg power and stamina.

It is important to note that this bill does not relate to other devices such as the Segway human transporter which does not meet any of the detailed requirements for a bicycle set forth in the CPSC rules.

I am aware of companies researching such electric bicycle product advancements, such as Wavecrest right here in Northern Virginia, and am excited about the prospects for the future.

I appreciate the strong efforts in the other body of Mr. CLIFF STEARNS, Mr. BILLY TAUZIN, Mr. HOWARD BERMAN, Mr. EARL BLUMENAUER, Mrs. LOIS CAPPS, Mr. DENNIS MOORE, Mr. MICHAEL OXLEY, Mr. CHARLES PICKERING, Mr. JAMES OBERSTAR and many others. In the Senate, I appreciate efforts of Chairman HOLLINGS, ranking member Senator MCCAIN and Senator BURNS, all of the Commerce Committee, in getting this bill to the Senate floor where it passed without opposition.

As I work on the massive reauthorization of our surface transportation